

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al.

Plaintiffs,

v.

HANMI USA, INC., et al.

Defendants.

Civil Action No. 11-760 (JAP)

MEMORANDUM ORDER

This is a Hatch-Waxman patent infringement action brought by Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively, “Astra” or “Plaintiff”) against defendants Hanmi, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively, “Hanmi” or “Defendant”). Presently before the Court is a motion by Hanmi to amend its noninfringement contentions pursuant to Local Patent Rules 3.6 and 3.7 to assert that its esomeprazole strontium product does not infringe the asserted claims of the ‘504 and ‘192 patents-in-suit because those claims do not encompass hydrated forms of the claims salts of the (-)-enantiomer of omeprazole.

Hanmi asserts that this new contention directly flows from (1) Hanmi’s Motion for Summary Judgment No. 4; (2) the positions Astra took in opposition to the motion; and (3) the Court’s ruling on the motion. According to Hanmi, it reasonably believed that Astra, by asserting the ‘504 and ‘192 patents against Hanmi’s esomeprazole strontium product, was taking the position that the asserted patents encompass hydrated forms of the claimed salts of the (-) – enantiomer of omeprazole. Based upon this, Hanmi moved for summary judgment claiming that

“hydrates” were neither described or enabled in the ‘504 patent. Astra opposed Hanmi’s motion, arguing that Hanmi was improperly focusing the inquiry on hydrates in violation of the prohibition on importing limitations into the claims. The Court denied Hanmi’s motion, finding that Hanmi had not convinced the Court it was entitled to judgment as a matter of law on the issue and there existed factual issues that precluded summary judgment. In support of its present motion, Hanmi argues that its proposed amendment does nothing more than conform its present contentions to the Court’s ruling and the parties’ respective positions.

Astra takes two alternative positions with regard to the instant motion. First, Astra states that it does not oppose the motion if the trial schedule in this action and a related action is extended. According to Astra, this is required in order to resolve an alleged claim construction issue that arises as a result of Hanmi’s proposed amendment. Astra, however, does not identify any specific term for which construction is required, but rather generally refers to the issue raised by Hanmi as one involving “claim scope.” Alternatively, Astra argues that the motion should be denied because Hanmi unreasonably delayed bringing its motion resulting in prejudice to Astra.

This district’s Local Patent Rules permit contentions to be amended “by order of the Court upon a timely application and showing of good cause.” Local Patent Rule 3.7. Pursuant to Rule 3.7, a court may permit a party to amend its invalidity contentions provided the following three elements are established: (1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party. *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 10-6108, 2012 WL 3133943 at *2 (D.N.J. July 30, 2012). The rule provides a “non-exhaustive” list of examples of circumstances that may support a finding of good cause including:

- (a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier

diligent search; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention; (d) disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement under L. Pat. R. 3.6(g) that requires response by the adverse party because it was not previously presented or reasonably anticipated; and (e) consent by the parties in interest to the amendment and a showing that it will not lead to an enlargement of time or impact other scheduled deadlines.

Local Patent Rule 3.7.

Our Local Patent Rules “are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.” *King Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 08–5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). However, while amendments to infringement contentions are not granted as liberally as requests for amendments to pleadings, the Patent Rules retain some degree of flexibility and are not intended to be “a straitjacket into which litigants are locked from the moment their contentions are served.” *Id.*

In the present matter, the Court finds the relevant considerations support granting Hanmi’s motion. As an initial matter, the Court finds good cause for the amendment. Hanmi’s proposed amendment is not an inappropriate response to the summary judgment record. It is at least arguable, as Hanmi contends, that Astra’s opposition to summary judgment motion No. 4 can be construed as attempting “to straddle the fence by asserting on the one hand that Hanmi was ‘importing a hydrates limitation into the claims,’ while on the other hand appearing to argue that the claims were generic to hydrates and other species.” Hanmi Br. at 5. Thus, in the interest of completeness and fairness, Hanmi should be permitted to assert that its proposed product does not infringe because the claims do not encompass hydrated forms of the claimed salts of esomeprazole.

Second, although Astra claims it would be unduly prejudiced by Hanmi's amendment, it fails to identify any specifics in that regard, stating only the general proposition that it is prejudiced because it has been "operating under Hanmi's original non-infringement contentions" since 2011 and has "developed its strategies" based on these contentions. To the extent there exists such a potential prejudice, a minor adjustment in the current trial schedule would mitigate it.¹

Third, the Court does not find the motion to be untimely. It was appropriate for Hanmi to wait until the Court issued its ruling on summary judgment before filing the present motion. Hanmi filed its present motion approximately 45 days after the Court's decision.

Finally, Astra misconstrues the Court's summary judgment decision in arguing that Hanmi should be precluded from "re-arguing" the "hydrates" issue because "this Court has already decided that 'hydrates' are not material to written description and enablement." The Court has not entered summary judgment in favor of Astra on this issue. Hanmi is correct that there has not been a final adjudication on the merits with respect to Hanmi's written description and enablement defenses, and those issues remain in the case for trial.

Consequently,

IT IS on this 23rd day of January 2013,

ORDERED that Hanmi's motion to amend its contentions is GRANTED; and it is further

ORDERED that Hanmi shall serve its amended contentions within 7 days from the date of this Order.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

¹ The parties and the Court had discussed setting an April 2013 trial date for this matter. Given the Court's current schedule as well as the present posture of the case and, that timeframe is no longer feasible. The parties are directed to work with the Magistrate Judge with respect to an updated schedule.